K112961
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OCT 31 2011

SECTION 6 - 510(k) SUMMARY

Submitted by:	Scion Cardio-Vascular, Inc. 14256 S.W. 119th Avenue Miami, FL 33186 Phone: (305) 259-8880 Fax: (305) 259-8878
Contact Person:	Lou Rose 14256 S.W. 119th Avenue Miami, FL 33186 Phone: (305) 259-8880 Ext 103 Fax: (305) 259-8878
Date Prepared:	September 14, 2011
Proprietary Name:	Clo-Sur^{PLUS} PAD^{TM}
Common Name:	Topical Hemostasis Pad
Classification:	Unclassified
Classification Name:	Topical Wound Dressing Pad
Predicate Device:	Scion Cardio-Vascular, Inc, K092552, CLO-SUR^{PLUS} P.A.D.,
Device Description:	The Scion Cardio-Vascular Clo-Sur^{PLUS} PAD^{TM} is a soft, non-woven topical pad that provides an optimal wound healing environment, combining an effective antibacterial barrier activity with exudates management. An optional slit Clo-Sur^{PLUS} PAD^{TM} allows for easier placement of the dressing around pins and tubes. Clo-Sur^{PLUS} PAD^{TM} has demonstrated in-vitro antibacterial activity for up to 144 hours (6 days) in certain strains shown to be detrimental to wound healing such as: Escherichia Coli, Staphylococcus Aureus, Streptococcus pyogenes, Pseudomonas aeruginosa, Bacillus cereus, Enterococcus faecium, Candida Albicans and Asperigillus brasiliensis. Clo-Sur^{PLUS} PAD^{TM} is a sterile topical hemostasis pad, packed in a foil pouch and sterilized by E-beam radiation to a 10^{-6} SAL.
Intended Use:	The Scion Cardio-Vascular Clo-Sur^{PLUS} P.A.D. is intended for the local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding

in patients following hemodialysis and for those on anticoagulation therapy.

The dressing is indicated for the following wounds: lacerations, abrasions, nose bleeds, surgical debridement sites, skin surface puncture sites, vascular procedure sites, and sites involving percutaneous catheters, tubes and pins.

Technological Characteristics

The Scion Cardio-Vascular Clo-Sur^{PLUS} PAD^{TM} is a soft, non-woven pad made of a proprietary formulation of poly-D-glucosamine and poly-N-acetylglucosamine derived from chitosan. The natural biological properties of this material gives the Clo-Sur^{PLUS} PAD^{TM} an advantage as an effective bacterial barrier while providing for an optimal wound healing environment.

Several biomedical applications of poly-D-glucosamine and poly-N-acetyglucosamine have been reported. The studies represent research on the safety and use of these materials, which have been published over a period of decades by scientists from around the world. The scientific literature satisfies the requirement that a general recognition of safety requires common knowledge about the substance throughout the scientific community. This formulation has many useful and advantageous properties in their application as a wound dressing, namely biocompatibility, biodegradability, hemostatic activity, anti-infectional activity.

The technological characteristics of the modified Clo-Sur^{PLUS} PAD^{TM} are the same as the predicate device. The Scion Cardio-Vascular modified Clo-Sur^{PLUS} PAD^{TM} works in the same manner as the approved predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Scion Cardio-Vascular, Inc.
% C2C Development, LLC
Mr. Craig Pagan
1050 W NASA Boulevard, Suite 136
Melbourne, Florida 32901

MAY 1 2012

Re: K112961
Trade/Device Name: Clo-Sur^{PLUS} P.A.D.
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 29, 2011
Received: October 4, 2011

Dear Mr. Pagan:

This letter corrects our substantially equivalent letter of October 31, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5 - INDICATIONS FOR USE STATEMENT

510(k) Number: K112961

Device Name: Clo-Sur^{PLUS} P.A.D.

INDICATIONS:

The Scion Cardio-Vascular Clo-Sur^{PLUS} P.A.D. is intended for the local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy.

The dressing is indicated for the following wounds: lacerations, abrasions, nose bleeds, surgical debridement sites, skin surface puncture sites, vascular procedure sites, and sites involving percutaneous catheters, tubes and pins.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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